ENSURING QUALITY AND SAFETY IN MEDICAL SERVICES: APPROACHES TO DEVELOPMENT AND PRACTICAL APPLICATION

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Abstract: To study the peculiarities of developing and implementing service quality standards to improve patient safety in healthcare facilities based on the latest research and existing standards. This study's theoretical and scientific approach aims to explore the combination of new patient safety capabilities based on monitoring and surveillance using ISO 9005:2015 and ISO 15189:2022 standards. Based on the analysed literature and current standards, the article considers the possibility of improving and implementing a monitoring system using wireless technologies – medical (contact and non-contact) and peripheral (non-contact) sensors. This is associated with the need for accreditation of medical laboratories and assessment of medical personnel's compliance with the requirements of current standards. The study's scientific novelty is to investigate the sequence of implementing documentation on standardisation and quality of services in healthcare facilities. This will ensure patient safety through a complex of measuring equipment (instruments and devices) and information technology (monitoring, data acquisition, and processing).

Keywords: Quality improvement, Information technologies, ISO 15189:2022, ISO 9001:2015, Sensors, Administration requirements, Technical requirements

1 Introduction

The modern healthcare system is facing rapid development of technologies, pharmaceuticals and innovative methods of diagnosis and treatment. Such a variety of the latest medical technologies, medicines, and medical services require effective methods to control their use, impact on the human body, and appropriateness. For this reason, standards and regulations have been developed to control the provision of medical services, which define the procedure and appropriateness of their use. This ensures the patient's right to receive quality medical care, responsibility, and safety in medical procedures, increasing public confidence in healthcare institutions.

Both patients and doctors have welcomed the standards of medical care. On the one hand, the standards aim to protect patients from side effects and unjustified medical interventions, and on the other hand, they regulate the procedure for providing medical care and serve as a guide for healthcare professionals. Conflict situations are resolved based on medical standards, which contributes to the objectivity of their resolution. Although medical standards are constantly being updated in parallel with changes in the medical field, the COVID-19 pandemic has shown its lack of effectiveness, especially in an emergency. That is why it is essential to study the implementation of standards in the medical sector by identifying criteria for assessing the quality of medical services and effectively monitoring the safety of medical care provided to patients through the introduction of innovative technologies.

The study aimed to determine the main requirements of ISO 9001:2015 and ISO 15189:2022 standards to ensure quality medical care, using the example of a digital model of a trauma centre and the introduction of innovative technologies for monitoring patients' condition.

To achieve this goal, the following tasks were formulated:

- To study the current literature on improving the quality of healthcare services and introducing innovations in medicine.
- Evaluate the requirements of international standards and their role in promoting patient safety in healthcare.
- To model the work of a trauma unit with the implementation of standards at the planning, creation, control and implementation stages.
- Identify the role of modern monitoring systems in ensuring quality patient care.

2 Literature review

The problem of assessing and improving the quality of healthcare provision to the population is an essential issue in the research of scientists from different countries, as quality healthcare ensures the country's well-being (Li et al., 2020; Akter et al., 2022). Improvements in the quality of healthcare services and the functioning of the healthcare system are ongoing due to the introduction of new reforms Pelzang and Hutchinson (2019). At the same time, healthcare reform is global and includes the goal of universal health coverage (UHC), which is defined as part of the Sustainable Development Goals (Debie et al., 2022; Berman et al. (2018). The most critical factor in healthcare reforms is the development of new and optimisation of existing standards of healthcare provision, such as EN ISO 9001, in line with the requirements of modern societal challenges (Kabalan, 2019; McGrath et al., 2021).

The importance of creating universal standards at the global level was demonstrated in the fight against the COVID-19 pandemic when the principles of the standards served as guidelines for the actions of medical personnel in the absence of data on effective treatments and overload of the medical system (Debie et al., 2022; Berman et al., 2018). Since standardisation in public policy contributes to overcoming crises, including the pandemic crisis and post-pandemic recovery, its implementation in the field of governance is essential (Prasetya et al., 2022). Applying standards in healthcare promotes compliance with the principles of patient safety, which minimises the negative impact of medical and diagnostic procedures, reduces the risk of adverse reactions, and thus helps reduce disability and mortality (Vaismoradi et al., 2020).

In the era of digitalisation and innovation, it is necessary to follow the requirements of standards, which primarily involve protecting patients from the rapid introduction of technologies in medical activities while determining the feasibility and validity of their use in individual cases. Legislation based on approved standards determines the population's safety when receiving medical services (Halamoda-Kenzaoui et al., 2019; Lleshi, 2020). Since the medical system is concerned with human life and health and has access to the patient's personal information, the ethical aspect plays a vital role in implementing the implemented standards involving multidisciplinary specialists (Nadziakiewicz & Mikolajczyk, 2019). Ethical issues are included at all stages of preparing a quality improvement strategy to prevent adverse events and iatrogenic errors during medical procedures (Silva et al., 2021).

The introduction of the latest technologies in the healthcare sector has increased citizens' access to healthcare services and contributed to the flexibility of the healthcare system. However, the issue of personal data protection and ethical principles remains controversial (Senbekov et al., 2020). In particular, scientists are investigating the impact on the quality of healthcare services of artificial intelligence, telemedicine, blockchain technologies, and smart devices as potential opportunities in the healthcare sector and assessing the negative consequences (Sittig et al., 2020; Senbekov et al., 2020) Among the opportunities is a new approach to patient monitoring, whereby indicators can be monitored not only by medical staff but also by the patient, which reduces the risk of injury and negative consequences for the patient while reducing the burden on healthcare workers (Han et al., 2023; Giuliano (2017). The medical system operates with a large amount of information in large databases, so it requires applications that can effectively

analyse it. The monitoring system can include devices that determine the patient's condition in real-time, such as bedside devices and computer networks in diagnostic rooms and doctors' offices. Uninterrupted operation and analysis of large databases are required for devices that monitor patient vitals. An example of an application that meets the above requirements is VitalPAD, designed for smartphones, allowing for the rapid transfer of information about a patient's condition and ensuring timely medical care (Flohr et al., 2018). Patient data management systems can collect approximately 1,000 data points per hour in intensive care units, which increases the doctor's workload, who spends more time interpreting the results and less time caring for the patient (Peine et al., 2023). That is why digital technologies should be carefully studied before being applied.

Some digital devices, such as mobile sensors that transmit information in real time, have become indispensable in treatment and prevention. Blood pressure monitors and electrocardiography help cardiologists identify life-threatening conditions and select effective therapy. These devices are valued in outpatient settings, as they allow for monitoring outside the hospital and in conditions close to the patient's daily activities. However, some authors doubt the safety of using wireless devices, especially outside the hospital, and emphasise the need to identify factors of potential harm in their use (Classen et al., 2021). Digital eHealth technologies have gained wide popularity in the healthcare system, facilitating effective communication between patients and healthcare providers, including online consultations, thus improving access to healthcare. Electronic tools make it easier to make an appointment with a doctor, avoid queues, optimise healthcare costs by reducing unnecessary consultations and hospitalisations, facilitate the storage and exchange of data between doctors of different specialities, and engage patients in autonomous manipulations and self-monitoring of medical recommendations (Dymyt, 2020). Despite the benefits of digital technologies, it is essential to ensure control over their appropriate implementation at different levels of healthcare provision and personal data protection.

The COVID-19 pandemic has confirmed the role of digitalisation in ensuring quality healthcare services by providing remote access to medical care as the healthcare system was overwhelmed. Electronic technologies have expanded the capabilities of the medical sector and were critical at the outpatient stage, as they helped to identify mild forms of the disease that did not require hospitalisation, and the use of devices such as pulse oximeters allowed the detection of threatening conditions and reduce the risk of respiratory failure and death, including during outpatient care (Sullivan et al., 2022). An effective monitoring system was also needed at the hospital stage, as patients' conditions could deteriorate sharply after short-term stabilisation, and the shortage of medical staff, including due to the spread of the disease among healthcare workers, required patients to be involved in monitoring their vital signs (Pronovost et al., 2022). Thus, the healthcare system focused on monitoring capabilities, namely the search for new patient monitoring systems that required accreditation and permits quickly (Noviantoro et al., 2020). Standards, including ISO 15189, which deals with laboratory diagnostics and regulates remote testing, also contributed to the fight against the pandemic, helping to expand laboratory testing capabilities (Pereira, 2020; Ilinca et al., 2023).

The large number of publications on innovative patient monitoring systems and their implementation in healthcare facilities confirms the relevance and timeliness of the topic in the context of rapid digitalisation. That is why it is essential to create standards for assessing the safety of monitoring systems to avoid adverse events and prevent the risk of potential harm. At the same time, the creation of quality standards for the use of monitoring systems will facilitate their widespread implementation in the healthcare sector and improve the quality of medical care.

3 Methods and materials

Our research was based on studying the main aspects of ISO 9001:2015 and ISO 15189:2022 standards and determining their role in improving the quality of healthcare services. We analysed the application of these standards in the healthcare sector and determined their effectiveness. The SO 9001:2015 standard is universal for various fields of activity, as it regulates improving the quality management system. Thus, this standard defines the critical aspects of ensuring the quality of medical care regarding regulating the management of a healthcare facility. At the same time, the scope of the standard is not limited to management; it also includes technical requirements, such as environmental conditions, equipment, personnel, characteristics of consumables, etc. The principle of ISO 9001:2015 includes the following steps: planning, design, measurement and implementation, and a process approach methodology. Since the basis of this standard is to improve the quality management system by following the recommendations, the implementation of ISO 9001:2015 helps to improve patient safety and reduce the risk of adverse events in the provision of medical services. ISO 15189:2022 is also an international standard that addresses the quality of laboratory and medical services in institutions licensed to provide these services. The main requirements for management and technical characteristics are shown in Table 1.

Table 1. Requirements for management requirements and technical specifications

Stages of the standardisation process	**Administrative requirements**	**Technical requirements**
Planning	Strategy development, organisation and management, quality system, preparation of documents and contracts	Environmental conditions, laboratory equipment, testing of materials and reagents
Creation	Organisation and management, document control and contract signing, technical documents, external services and supplies, expert opinions	Expert proceedings, quality assurance of expert procedures
Controlling the results	Document control, identification and control of nonconformities, advisory services, corrective actions, quality improvement	Established guidelines carry out inspections
Implementation	Complaint handling, preventive measures, continuous improvement and quality assurance, internal audit and management review	Reporting on results

Source: Allen (2013)

To plan the implementation of the standards and check the quality of monitoring of patient's vital signs, digital modelling was carried out, including creating a 2D and 3D model of a medical facility providing trauma care. The model was created using computer-aided design software. By implementing standards, we created zoning for different medical services and justified the need to allocate these zones. When developing the model, we were guided by the principles of optimising the location of wards, diagnostic rooms and staff rooms. The model provided different possibilities for a medical facility's workload, considering resources and staff placement. The programme set the parameters of functional rooms, avoiding places that could impede the mobility of a trauma patient who can be transported on a stretcher or wheelchair. Sensors were placed in the model of

the trauma unit for potential patient monitoring, and the optimal location of wards and diagnostic rooms was determined.

The study included a digital component without the involvement of actual patients. However, we used data from the literature and healthcare facilities on the possibilities of remote monitoring in hospital wards, including intensive care units. We predicted the feasibility of using modern monitoring systems in the developed model to identify threatening conditions of patients and prevent the spread of infections. This demonstrated the importance of the modelling results during the COVID-19 pandemic and the increase in seasonal morbidity, including influenza.

The development of the digital model involved taking into account the specifics of the organisation of medical facilities, including trauma departments. The computer program set the parameters of the premises and monitoring sensors, which were subject to mathematical calculations to build an accurate model. The parameters of the patient's physiological functions, such as blood pressure, pulse, respiratory rate, temperature, and electrocardiography data taken from the healthcare database and other research databases, were not subject to disclosure. The principles of medical confidentiality and ethical standards were followed when working with patient data.

4 Results

To achieve the study's objectives, we analysed the human resources management standards and ISO 15189:2022 requirements to assess the quality of laboratory tests and the organisation of laboratory work. The data are presented in Tables 2 and 3. The criteria for determining the quality of service provision, instructions, and recommendations for compliance with the standards are described.

Table 2. Requirements for compliance with the management standards of medical institutions performing laboratory diagnostics

Requirement	**Criteria that meet them**
Organisation and management	Organisation of the workplace, development of job descriptions, provision of certified equipment, familiarisation with equipment operating instructions, occupational safety, prevention of occupational injuries and equipment damage.
Quality control system	All processes are clearly regulated and described in detail in work instructions. Staff are familiarised with job descriptions and sign a commitment to comply with them. Equipment operating instructions contain information on calibration, properties, and reagent handling. Before use, the equipment is tested, and a certificate is issued with a specified period of operation.
Documentation	All laboratory processes are subject to accounting and documentation. This includes instructions, safety rules, logbooks for research, reagents, sanitary procedures, quality certificates, equipment operation procedures, and contracts with maintenance firms, consultants, and partners.
Testing by control laboratories	All trials are documented, but the control laboratories can duplicate them in case of data loss. Control laboratories also play a role in conflict situations, as they ensure that the results are delivered to the patient while maintaining the confidentiality of personal data.
External services and materials	Procurement of reagents and systems, cooperation with partners, regulated by contracts.
Consultancy services	Consultations on the use of equipment, continuing professional development, technical courses, and conferences on introducing innovations in laboratory diagnostics. Medical personnel can provide advice on the collection of biological materials and the procedure for preparing for laboratory tests but are not involved in the interpretation of the results.
Analysis of complaints and suggestions	A log of complaints and suggestions is kept, which are reviewed. Based on the complaints' results, steps are planned to resolve them, which are subject to further documentation.
Correcting inconsistencies	As part of the continuous quality control of laboratory tests, inaccuracies related to improper operation and maintenance of equipment, quality of reagents and systems, professional competence of personnel, etc., are identified.
Controlling/preventing nonconformities	If a nonconformity is identified, it is immediately eliminated and recorded in the continuous quality monitoring log. Nonconformity prevention includes preventive methods, periodic inspections, and test checks.
Internal audit of the quality and management system	It involves checking the compliance of all processes with international standards and internal regulations, which are based on generally accepted standards but contain adjustments depending on the specifics of the equipment, personnel qualifications, working conditions, etc.

Source: Allen (2013)

Table 3. Technical requirements for laboratories by ISO 15189:2022

Staff	The staff performs their activities according to their job descriptions. Staff is provided with access to documentation within their authority's scope. Records and documentation are kept according to the approved rules. Qualification checks, continuous professional development, and compliance with occupational safety rules are provided.
Environmental conditions	Ensuring the requirements for the premises where laboratory diagnostics are carried out, zoning of material collection, diagnostics, documentation, and storage of materials or reagents, the parameters of ventilation, air temperature, humidity, lighting, etc., are considered. Availability of conditions for storing materials and reagents under a special temperature regime.
Equipment	Certified and licensed equipment with available instructions for the regulation of operation and maintenance. A logbook for the number of cycles, sanitary breaks, reagent changes, and calibration. Conducting current and periodic inspections, as well as in case of malfunctions.
Preliminary research procedure	This includes collecting patient data, preparing for specimen collection, providing accessibility to the manipulation room for patients with reduced mobility, providing test systems, storing and transporting specimens, etc. Mandatory documentation of all processes and stages of laboratory diagnostics, including patient's personal data and test results; samples may be temporarily stored until test results are available to allow for retesting in case of equipment

	failure. All samples and results are recorded in the results log and can be recovered in case of loss of results.
Research procedures	All research processes are subject to standardisation and verification. They are recorded at each stage and specified in the instructions on the rules for their conduct, material characteristics, and interpretation of results. All procedures are documented and require replacement or updating in case of deviation from the norms.
Quality assurance of procedures	Adherence to instructions for biological material samples, reagents, research stages, and standardisation of results is essential. Documentation of deviations from the norm is mandatory.
Reporting on results	All processes are recorded appropriately, using generally accepted nomenclature and classification. Reports are generated at specified intervals, taking into account data from accounting documents, discrepancy reports, complaints and problem resolution reports.

Source: Allen (2013)

Figure 1 shows the digital layout of a trauma centre, which includes zoning according to the urgency of care. There are separate departments for routine outpatient and emergency care, an admission department, a waiting room, and diagnostic rooms, including express laboratories, X-ray rooms, and computed tomography. There are manipulation rooms, dressing rooms, and wards for inpatient treatment. The facility can treat 180 to 220 patients with various diseases and injuries daily. Zoning plays a role in the quality management system by separating outpatient and emergency care, which allows for the simultaneous provision of services at different levels without causing mutual inconvenience. There are separate X-ray diagnostic rooms for patients from the emergency and outpatient units. The staff rooms are located by the zoning for easy monitoring of patients' condition. This model of the trauma unit includes the implementation of quality medical care standards at the stage of patient registration, optimisation of staff placement and management, provision of equipment and work planning.

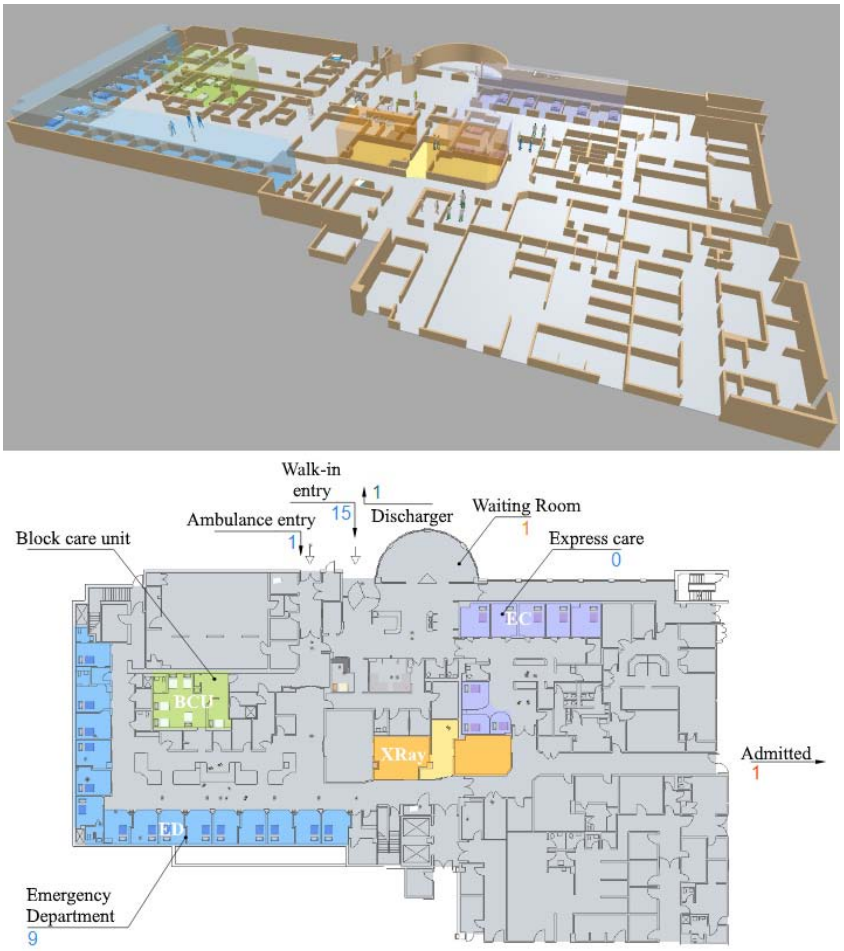

Figure 1. A digital model of the Trauma Profile Medical Centre

Visualisation of the trauma centre model in 2D and 3D images helps to assess the accessibility of trauma care and potential medical services that can be provided within the facility. The central location of diagnostic rooms facilitates access to diagnostics for patients from different departments. The absence of separate diagnostic areas for outpatients and emergency patients is due to the requirements of wall permeability in these rooms. However, it is a positive factor that there are separate X-ray rooms for outpatients and emergency patients, as this reduces the risk of disease spread among these groups of patients.

Within the walls of the modelled facility, it is possible to provide care to more than 180 patients per day, some of whom may be day or round-the-clock inpatients. Therefore, despite the advantages of zoning with the placement of medical staff, it is difficult to ensure effective simultaneous monitoring of a large number of patients in real-time. The problem of effective

monitoring can be solved by using wireless monitoring devices connected to a single hospital network and providing information on vital signs. The principle of remote monitoring systems is to collect information using touch sensors and transmit it uninterruptedly to hospital computers, which are accessible to doctors at the hospital or to the patient's devices, such as smartphones or smartwatches.

An analysis of the layout of the departments of a trauma centre shows the importance of zoning in achieving the basic principles of quality standards for medical care. The layout of zones of different functionality ensures staff work organisation and appropriate equipment availability. Separation of emergency and outpatient patients prevents the spread of infections between these groups of patients. In addition to zoning planning, it is essential to ensure the conditions for providing medical services, including standards for lighting, air temperature, humidity and ventilation. The departments' regulations should provide for the sanitisation of premises, work surfaces, and equipment, with mandatory quartzing of wards, manipulation rooms, and dressing rooms by established schedules. The requirements of the standards should be posted in the wards and made available to medical staff. The creation of 2D and 3D diagrams of a medical facility should be carried out at the planning stage with the relevant documentation and taking into account ISO 9001:2015 and ISO 15189:2022 standards.

Patient monitoring system

Figure 2 schematically shows the layout of sensors and devices to which information is transmitted. Depending on their location on the body's topographical points, the sensors are divided into electroencephalography, airflow and respiratory rate, electrocardiography, patient position, blood pressure, pulse oximeter with heart rate and blood oxygen saturation, electromyography, motion sensor, etc.

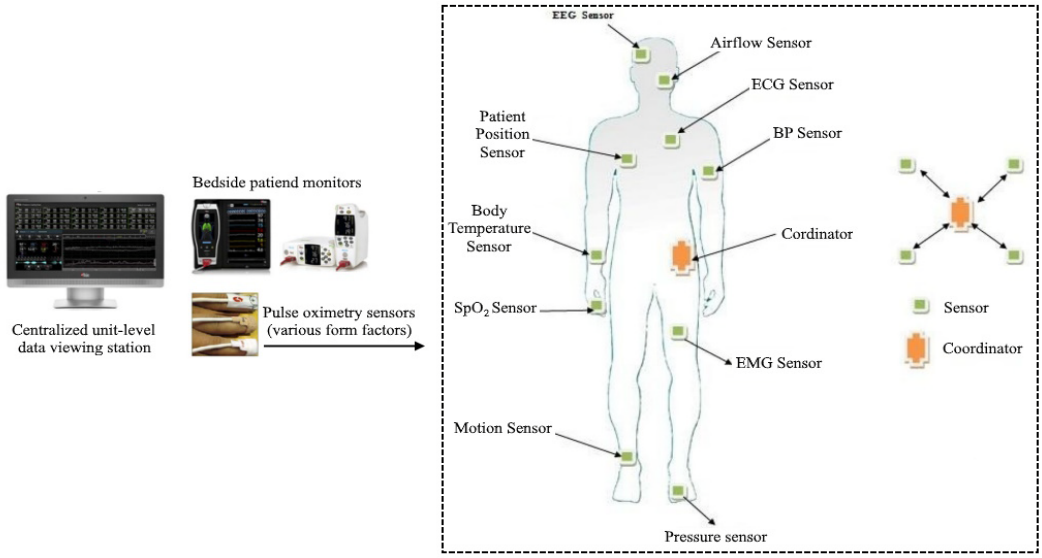

Figure 2. A scheme for placement of sensors and devices for transmission and interpretation of the results of the patient condition monitoring system
Source: Singh et al. (2021)

Remote sensors (Figure 2) are widely used in medical practice. Most of the sensors are not expensive and reduce the burden on medical staff when measuring blood pressure, saturation, body temperature, etc. The monitoring system for inpatient wards is usually represented by bedside monitors with sensors connected to them (Singh et al., 2021). Moreover, such automated measurement can be controlled by setting the multiplicity of measurements and storing information. For example, for intensive care units, it is essential to continuously measure these vital parameters with the ability to respond to changes promptly. For therapeutic and surgical departments, monitors set the parameters for hourly measurement of indicators. This monitoring limitation is essential to extend the equipment's life and reduce unnecessary information that needs to be interpreted. The same applies to the storage of monitoring data, which should be concise to reduce the time spent reviewing and interpreting the results by the doctor. More important, especially for intensive care units, is the presence of a signal of a threatening change in a physiological parameter, such as a drop in saturation, acceleration or deceleration of pulse rate, respiration, increase or decrease in blood pressure, etc.

Wireless monitoring systems also expand diagnostic capabilities for outpatients. Combining a wireless sensor network with a local hospital system makes collecting patient data at home possible, considering the usual loads and stress levels. Such a system is valuable for diagnosing hypertension and angina and determining the effectiveness of hypertension and coronary heart disease therapy. Remote monitoring reduces the time required to diagnose and select therapy in patients, which is carried out as part of a routine medical examination.

Today, medical sensors have significantly expanded their application scope and perform diagnostic and therapeutic functions. Diagnostic sensors can be connected to monitors, such as pulse oximeters, blood pressure cuffs, and topographic point sensors for electrocardiography, electromyography, and electroencephalography. Therapeutic sensors are patches containing a medicine of a specific concentration delivered to the target tissue over a certain period. Another example of therapeutic sensor functionality is the automatic switching between defibrillators and stimulator sensors for pain management.

The principle of wireless sensors' operation involves sending information about physiological parameters through a body control unit that coordinates data collection. The data is transmitted by connecting the sensors to a medical server via the Internet or a local network. Bluetooth or Wi-Fi is used for data transmission. The first level of data transmission is when the body control unit receives information. The second level involves data transfer to the patient's smartphone or personal computer, which hosts the coordinator app. The third level is the transfer of data to a medical facility, where further analysis and interpretation of the data takes place. The sensors can be synchronised with the patient's smart devices, such as a phone or a watch. Wireless sensors can detect physiological health indicators (physical activity based on motion sensors) and

behavioural patterns (nutrition based on calorie intake and loss, daily routines based on movement, and sleep and activity periods). Other capabilities of the sensors include speech and vision amplification. Thus, the modern capabilities of digital technologies are of great importance in monitoring the patient's physiological parameters and play an essential role in patient safety.

5 Discussion

The ISO 9001:2015 and ISO 15189:2022 standards are international and generally accepted guidelines aimed at patient safety and reducing adverse events related to the human factor or the conditions of medical care. That is why standards are mandatory, and detailed guidelines are provided at medical facilities' planning, creation, control, and operation stages, including laboratories. The development of standards is a continuous process that includes implementing new methods, equipment, and personnel management principles to improve the quality of healthcare services. That is why compliance with the requirements of the standards is not a formality or a limiting factor in the work of medical institutions but rather a developed recommendation to avoid adverse effects on patients, medical staff and the environment (Fedele et al., 2022).

The development of digitalisation also affects the healthcare system, for which the introduction of innovative technologies is promising and requires detailed study before being applied in practice, as the cost of a mistake concerns the patient's safety. That is why IT systems related to patient care must be reliable, safe and high-quality (Burgers et al., 2020; Sittig et al., 2020). Control over the effectiveness of IT systems in healthcare facilities should include a multi-level check to avoid errors and negative consequences for patient safety (Wienert, 2019).

Singh and Sittig (2016) have developed a strategy for predicting the security of digital technologies in the healthcare system called Healthcare IT Security (HITS), which aims to identify potential risks associated with IT systems. This model determines the effectiveness of IT programmes in performing their tasks and simulates situations of different ways of using digital tools, including misuse, to clearly identify potential dangers in the case of misuse of IT. This model of prevention, while costly, allows for the identification of programme deficiencies before they can cause harm to patients.

However, the opportunities offered by digital technologies for the healthcare industry outweigh the potential risks, especially in the case of reporting, quality control, and optimisation of healthcare facilities. Digital technologies allow for the analysis of an extensive database of statistical parameters and the identification of inconsistencies and gaps in the institution's work and personnel management. Automated checks can identify the cause and effect of adverse incidents, improving healthcare service quality (Silva et al., 2021).

Nadziakiewicz and Mikolajczyk, 2019, describe the complexity of determining the effectiveness of medical institutions by individual indicators. After all, statistical reporting parameters allow us to directly determine the economic feasibility of a specific list of medical services and determine the duration and outcome of treatment. However, it is impossible to consider the patient's quality of life after treatment and satisfaction with the facility. Another aspect is the assessment of medical care, which may not justify itself due to low demand for the service and high costs. It is crucial for the lives of patients who need it immediately, such as an urgent operation. In such cases, it is crucial to use the principles of international standards, which primarily assess the benefits to patient safety, regardless of economic feasibility.

Although current monitoring systems have not been subjected to multi-stage testing, most sensors are certified and approved for use in healthcare facilities. Moreover, more convenient, cost-effective and reliable sensors are being sought. Hatamie et al. (2020) describe the prospect of using textile-based physiological monitoring sensors, which will contribute to greater convenience, accuracy and reliability of parameter recording. Adeniyi et al. (2021) studied the prospect of the Internet of Medical Things (IoMT), which is a combination of a network of body sensors with healthcare devices that allows detecting deviations of physiological parameters from the norm as a disease prevention measure.

Thus, the application of international standards is critical for the work of healthcare facilities to maintain patient safety, as careful adherence to the requirements of the standards minimises the risks associated with unforeseen factors, including human error. Following instructions when implementing IT technologies is also necessary, as the cost of a mistake is high and involves patient personal data, which is a medical secret. Although digitalisation has opened up new opportunities for monitoring patient safety, it still requires the study of long-term results, identification of potential errors and improvement by international standards.

6 Conclusion

Implementing ISO 9001:2015 and ISO 15189 is essential for patient safety, as it provides requirements that address all factors affecting the quality of medical care and laboratory diagnostics. The requirements of the standards are mandatory, as compliance with these requirements reduces the risk of adverse events in the provision of medical services. In the age of advanced digital technologies, it is necessary to consider and adapt standards for the implementation of IT in the healthcare sector. Although digital devices, including sensors for monitoring patients' condition, have significantly improved the quality of medical care by reducing the workload of medical staff, they require detailed analysis before being used in medical facilities.

Developing a digital model of a trauma centre includes planning the creation and operation of a medical facility by the requirements of the standards, including mathematical calculations to optimise space, room quality and zoning. As the model envisages medical care for more than 180 patients, the possibilities and prospects of using modern systems for monitoring patients' physiological parameters were considered. The modelling makes it possible to plan and evaluate the efficiency of patient registration, medical care at various levels, and diagnostics with the effective involvement of medical staff and resources of the medical institution. The developed model has revealed the benefits of effective zoning of functional areas of a medical facility, staff involvement, and patient monitoring systems to prevent the spread of infectious diseases and complications and prevent conditions that threaten the life and health of patients. This observation is essential for an increase in the seasonal incidence of influenza and COVID-19.

Evaluating the performance of medical institutions based on the creation of the proposed digital model is a promising method that can be used at the strategic planning stage, which allows for minimising negative factors and correcting inconsistencies, and at the stage of putting a medical institution into operation. At the same time, modelling can also be applied to existing facilities, for example, before modernising patient monitoring systems or assessing the quality of healthcare services.

Literature:

1. Adeniyi, E. A., Ogundokun, R. O., & Awotunde, J. B.: IoMT-based wearable body sensors network healthcare monitoring system. In *IoT in healthcare and ambient assisted living*, 2021, pp. 103–121. https://doi.org/10.1007/978-981-15-9897-5
2. Akter, S., Babu, M. M., Hossain, M. A., & Hani, U.: Value co-creation on a shared healthcare platform: Impact on service innovation, perceived value and patient welfare. *Journal of Business Research*, 2022, 140, 95–106. https://doi.org/10.1016/j.jbusres.2021.11.077
3. Allen, L. C.: Role of a quality management system in improving patient safety-laboratory aspects. *Clinical Biochemistry*, 2013, 46(13-14), 1187–1193. https://doi.org/10.1016/j.clinbiochem.2013.04.028

4. Berman, L., Raval, M. V., & Goldin, A.: Process improvement strategies: Designing and implementing quality improvement research. In *Seminars in pediatric surgery*, 2018, December, 27(6), 379–385. WB Saunders. https://doi.org/10.1053/j.sempedsurg.2018.10.006
5. Burgers, J., van der Weijden, T., & Grol, R.: Clinical practice guidelines as a tool for improving patient care. In *Improving patient care: the implementation of change in health care*, 2020, pp. 103–129. https://doi.org/10.1002/9781119488 620.ch6
6. Classen, D. C., Munier, W., Verzier, N., Eldridge, N., Hunt, D., Metersky, M., ... & Battles, J.: Measuring patient safety: the Medicare patient safety monitoring system (past, present, and future). *Journal of Patient Safety*, 2021, 17(3), e234–e240. https://doi.org/10.1097/PTS.0000000000000322
7. Debie, A., Khatri, R. B., & Assefa, Y.: Successes and challenges of health systems governance towards universal health coverage and global health security: a narrative review and synthesis of the literature. *Health research policy and systems*, 2022, 20(1), 50. https://doi.org/10.1186/s12961-022-00858-7
8. Dymyt, M.: The Role of eHealth in the Management of Patient Safety. *Journal of e-health Management*, 2020, 2020, 1–13. https://doi.org/10.5171/2020.341252
9. Fedele, A., Avruscio, G., Barison, L., & Scipioni, A.: Standards to Support ISO 15189 Implementation for Medical Laboratories Accreditation. *Clin Case Rep Int.*, 2022, 6, 1310.
10. Flohr, L., Beaudry, S., Johnson, K. T., West, N., Burns, C. M., Ansermino, J. M., ... & Görges, M.: Clinician-driven design of vital pad-an intelligent monitoring and communication device to improve patient safety in the intensive care unit. *IEEE journal of translational engineering in health and medicine*, 2018, 6, 1–14. https://doi.org/10.1109/JTEHM.2018.2812162
11. Giuliano, K. K.: Improving patient safety through the use of nursing surveillance. *Biomedical instrumentation & technology*, 2017, 51(s2), 34–43. https://doi.org/10.2345/0899-8205-51.s2.34
12. Halamoda-Kenzaoui, B., Holzwarth, U., Roebben, G., Bogni, A., & Bremer-Hoffmann, S.: Mapping of the available standards against the regulatory needs for nanomedicines. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology*, 2019, 11(1), e1531. https://doi.org/10.1002/ wnan.1531
13. Han, S., Xu, M., Lao, J., & Liang, Z.: Collecting Patient Feedback as a Means of Monitoring Patient Experience and Hospital Service Quality-Learning from a Government-led Initiative. *Patient preference and adherence*, 2023, pp. 385–400. https://doi.org/10.2147/PPA.S397444
14. Hatamie, A., Angizi, S., Kumar, S., Pandey, C. M., Simchi, A., Willander, M., & Malhotra, B. D.: Textile-based chemical and physical sensors for healthcare monitoring. *Journal of the Electrochemical Society*, 2020, 167(3), 037546. https://doi.org/10.1149/1945-7111/ab6827
15. Ilinca, R., Chiriac, I. Aţesdu D. A., Ganea, I., Hristodorescu-Grigore, S., & Dănciulescu-Miulescu, R. E.: Understanding the key differences between ISO 15189:2022 and ISO 15189:2012 for an improved medical laboratory quality of service. *Revista Romana de Medicina de Laborator*, 2023, 31(2), 77–82. https://doi.org/10.2478/rrlm-2023-0011
16. ISO 9001:2015 Quality Management Systems – Requirements. 2015. https://www.iso.org/standard/62085.html [Accessed 24 July 2023].
17. ISO 15189:2022 Medical laboratories – Requirements for quality and competence. 2022. https://www.iso.org/standard/76677.html [Accessed 24 July 2023].
18. Kabalan, W.: Implementation of ISO 9001: 2015 quality management system in a clinical [sic] clinical laboratory in the Southern suburb of Beirut. 2019.
19. Li, X., Krumholz, H. M., Yip, W., Cheng, K. K., De Maeseneer, J., Meng, Q., ... & Hu, S.: Quality of primary health care in China: challenges and recommendations. *The Lancet*, 2020, s395(10239), 1802–1812. https://doi.org/10.1016/S0140-6736(20)30122-7
20. Lleshi, S.: The Effectiveness of QMS Implementation in Applying of Quality Health Care for Patients in Health Institutions of Kosovo. *European Journal of Medicine and Natural Sciences*, 2020, 3(1), 26–34.
21. McGrath, S. P., McGovern, K. M., Perreard, I. M., Huang, V., Moss, L. B., & Blike, G. T.: Inpatient respiratory arrest associated with sedative and analgesic medications: impact of continuous monitoring on patient mortality and severe morbidity. *Journal of Patient Safety*, 2021, 17(8), 557. https://doi.org/10.1097/PTS.0000000000000696
22. Nadziakiewicz, M., & Mikolajczyk, A.: The quality and safety of health care services. *Management Systems in Production Engineering*, 2019, 27(2), 100–104. https://doi.org/10.1515/mspe-2019-0017
23. Noviantoro, R., Maskuroh, N., Santoso, B., Fahlevi, M., Pramono, R., Purwanto, A., ... & Munthe, A. P.: Did the quality management system ISO 9001 version 2015 influence business performance? Evidence from Indonesian hospitals. Journal Scopus, 2020.
24. Peine, A., Gronholz, M., Seidl-Rathkopf, K., Wolfram, T., Hallawa, A., Reitz, A., ... & Martin, L.: Standardised Comparison of Voice-Based Information and Documentation Systems to Established Systems in Intensive Care: A Crossover Study. *JMIR Medical Informatics*, 2023, 11, e44773. https://doi.org/10.2196/44773
25. Pelzang, R., & Hutchinson, A. M.: Patient safety policies, guidelines, and protocols in Bhutan. *The International Journal of Health Planning and Management*, 2019, 34(2), 491–500. https://doi.org/10.1002/hpm.2729
26. Pereira, P.: ISO 15189: 2012 Medical laboratories-Requirements for quality and competence. Westgard QC: Madison, WI, USA, 2020.
27. Prasetya, B., Restu Wahono, D., Yopi, & Prasetya, C.: Innovation Opportunity and Challenge of Standardisation in Response to COVID-19 Pandemic and the Socio-Economic Impact: A Case Study in Indonesia. *Standards*, 2022, 2(1), 66–82. https://doi.org/10.3390/standards2010006
28. Pronovost, P. J., Cole, M. D., & Hughes, R. M.: Remote patient monitoring during COVID-19: an unexpected patient safety benefit. *Jama*, 2022, 327(12), 1125–1126. https://doi.org/10.1001/jama.2022.2040
29. Senbekov, M., Saliev, T., Bukeyeva, Z., Almabayeva, A., Zhanaliyeva, M., Aitenova, N., ... & Fakhradiyev, I.: The recent progress and applications of digital technologies in healthcare: a review. *International journal of telemedicine and applications*, 2020, (1), 8830200. https://doi.org/10.1155/2020/8830200
30. Silva, K. T. D., Filgueiras, R. C., Gamaski, R., & Göttems, L. B. D.: Prototype for monitoring incidents in the health services: innovation for patient safety. *Texto & Contexto-Enfermagem*, 2021, 29. https://doi.org/10.1590/1980-265x-tce-2019-0185
31. Singh, H., & Sittig, D. F.: Measuring and improving patient safety through health information technology: The Health IT Safety Framework. *BMJ Quality & Safety*, 2016, 25(4), 226–232. https://doi.org/10.1136/bmjqs-2015-004486
32. Singh, P., Raw, R. S., & Khan, S. A.: Development of novel framework for patient health monitoring system using VANET: an Indian perspective. *International Journal of Information Technology*, 2021, 13, 383–390. https://doi.org/10.1007/s41870-020-00551-4
33. Sittig, D. F., Wright, A., Coiera, E., Magrabi, F., Ratwani, R., Bates, D. W., & Singh, H.: Current challenges in health information technology-related patient safety. *Health Informatics Journal*, 2020, 26(1), 181–189. https://doi.org/10.1177/1460458218814893
34. Sullivan, Z. P., Zazzeron, L., Berra, L., Hess, D. R., Bittner, E. A., & Chang, M. G.: Noninvasive respiratory support for COVID-19 patients: when, for whom, and how? *Journal of Intensive Care*, 2022, 10(1), 3. https://doi.org/10.1186/s40560-021-00593-1
35. Vaismoradi, M., Tella, S., Logan, P. A., Khakurel, J., & Vizcaya-Moreno, F.: Nurses' adherence to patient safety principles: A systematic review. *International journal of environmental research and public health*, 2020, 17(6), 2028. https://doi.org/10.3390/ijerph17062028
36. Wienert, J.: Understanding health information technologies as complex interventions with the need for thorough implementation and monitoring to sustain patient safety. *Frontiers in ICT*, 2019, 6, 9. https://doi.org/10.3389/fict.2019 .00009

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